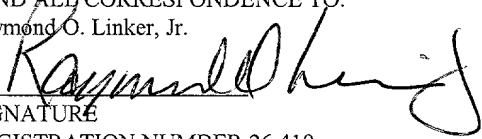
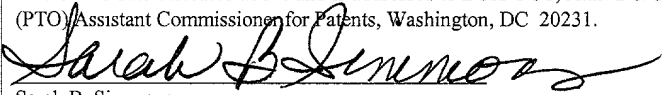


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12/21/00

414 Rec'd PCT/PTO 21 DEC 2000

PCT

FORM PTO-1390 (REV 10-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 33339/207111
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO (If known, see 37 C.F.R. 1.5) To be assigned <b>09/720569</b>
INTERNATIONAL APPLICATION NO PCT/FR99/01489	INTERNATIONAL FILING DATE June 22, 1999	PRIORITY DATE CLAIMED June 22, 1998	
TITLE OF INVENTION INGESTIBLE ELEMENTS			
APPLICANT(S) FOR DO/EO/US Philippe Douaire; Sandrine Vincensini			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).</p> <p>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11. To 16. Below concern other document(s) or information included:</b></p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input type="checkbox"/> Other items or information.</p>			

U.S. APPLICATION NO. (if known) See 37 CFR 1.530 To be assigned <b>09/720569</b>		INTERNATIONAL APPLICATION NO PCT/FR99/01489		ATTORNEY'S DOCKET NUMBER 33339/207111	
17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS	PTO USE ONLY
<b>Basic National Fee (37 CFR 1.492(a)(1)-(5)):</b> Neither international preliminary examination fee (37 CFR 1.482) nor International search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO <span style="float: right;"><b>\$1,000.00</b></span>  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO <span style="float: right;"><b>\$860.00</b></span> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search (37 CFR 1.445(a)(2)) paid to USPTO <span style="float: right;"><b>\$710.00</b></span> International preliminary examination fee (37 CFR 1.482) paid to USPTO <span style="float: right;"><b>\$690.00</b></span> But all claims did not satisfy provisions of PCT Article 33(1)-(4) <span style="float: right;"><b>\$100.00</b></span> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) <span style="float: right;"><b>\$100.00</b></span>					
<b>ENTER APPROPRIATE BASIC FEE AMOUNT</b> =				<b>\$ 860.00</b>	
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				<b>\$</b>	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	10 -20 =	0	<b>X \$18.00</b>	<b>\$ 0.00</b>	
Independent Claims	1 - 3 =	0	<b>X \$80.00</b>	<b>\$ 0.00</b>	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			<b>+ \$270.00</b>	<b>\$</b>	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 860.00</b>	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by one-half.				<b>\$</b>	
<b>SUBTOTAL =</b>				<b>\$ 860.00</b>	
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				<b>\$</b>	
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 860.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property +				<b>\$</b>	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 860.00</b>	
				Amount to be Refunded	<b>\$</b>
				Charged	<b>\$</b>
a. <input checked="" type="checkbox"/> A check in the amount of <b>\$ 860.00</b> to cover the above fees is enclosed.  b. <input type="checkbox"/> Please charge my Deposit Account No. 16-0605 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed  c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 16-0605.					
Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: Raymond O. Linker, Jr.  SIGNATURE REGISTRATION NUMBER 26,419 <b>ALSTON &amp; BIRD LLP</b> Post Office Drawer 34009 Charlotte, NC 28234 Tel. Charlotte Office (704) 331-6000 Fax Charlotte Office (704) 334-2014 <b>Customer Number 000826</b>			<b>"Express Mail"</b> Mailing Label Number EL 432822825 US Date of Deposit: December 21, 2000  I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to BOX PCT, Attn: DO/US (PTO) Assistant Commissioner for Patents, Washington, DC 20231.  Sarah B. Simmons		

09/720569

526 Rec'd PCT/PTO 21 DEC 2000

Attorney's Docket No. 33339/207111

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

In re: Philippe Douaire et al.  
International Appl. No.: PCT/FR99/01489  
International Filing Date: June 22, 1999  
For: INGESTIBLE ELEMENTS

Attn: DO/US

December 21, 2000

Box PCT  
Assistant Commissioner of Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Sir:

Please amend the above-identified application as follows:

In The Claims:

1. An element suitable for being ingested, comprising at least one air-passing channel [(3)] making it possible to avoid choking in the event of being swallowed the wrong way.
2. An element according to claim 1, wherein the channel [(3)] is cylindrical or substantially cylindrical.
3. An element according to claim 2, wherein the channel [(3)] has a diameter lying in the range 0.5 mm to 6 mm [, preferably in the range 1 mm to 4 mm, and more preferably in the range 2 mm to 3 mm].
4. An element according to [any preceding claim] claim 1, wherein said element is a medicine for taking orally.
6. An element according to claim 4 [or 5], wherein said element is a coated tablet.

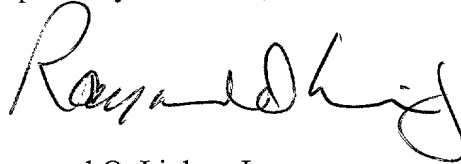
7. An element according to claim 6, wherein the coating covers the walls of the air-passing channel [(3)].

10. An element according to [any one of claims 1 to 3] claim 1, wherein said element is a foodstuff.

REMARKS

The above amendments are made to more clearly define the invention under United States practice. Please enter this amendment prior to calculation of the filing fee.

Respectfully submitted,



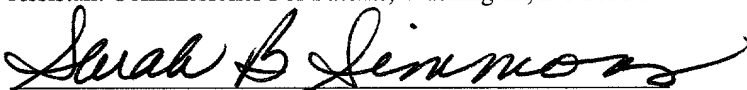
Raymond O. Linker, Jr.  
Registration No. 26,419

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Post Office Drawer 34009  
Charlotte, NC 28234  
Tel Charlotte Office (704) 331-6000  
Fax Charlotte Office (704) 334-2014

**CERTIFICATE OF EXPRESS MAILING**

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Sarah B. Simmons

CLT01/4457267v1

INGESTIBLE ELEMENTS

The present invention relates mainly to elements that can be ingested such as sweets, candies, dried fruit, peanuts, or medicines to be taken orally.

5 Medicines, such as tablets, pills, or capsules, for example, and also certain foodstuffs such as, for example, nuts, sweets, candies, ice cubes, sugar lumps, confectionery, and chocolates are presented in the form of a relatively hard solid piece which, when swallowed  
10 the wrong way, in particular by an old person or by a child, and in particular a young child, runs the risk of blocking the airways, giving rise to choking.

Consequently, an object of the present invention is to provide ingestible elements that do not present a risk  
15 of choking when they are swallowed the wrong way.

Another object of the present invention is to provide such ingestible pieces of a shape that makes them easier to swallow.

Another object of the present invention is to  
20 provide medicines presenting active principle release properties that are optimized as a function of the prescribed treatment.

According to the present invention, these objects are achieved by an element of the medicine, sweet, candy,  
25 nut, dry charcuterie, or cheese type or the like in which at least one air flow channel is formed.

The invention will be better understood from the following description and the accompanying figures given as non-limiting examples, and in which:

30 • Figure 1 is a perspective view of a first embodiment of a tablet in accordance with the present invention;

• Figure 2 is a perspective view of a second embodiment of a tablet in accordance with the present  
35 invention;

• Figure 3 is a perspective view of a preferred embodiment of a tablet in accordance with the present invention;

5 • Figure 4 is a perspective view of a preferred embodiment of a capsule in accordance with the present invention prior to being assembled;

• Figure 5 is an analogous view of the Figure 4 capsule after it has been assembled;

10 • Figure 6 is a section view of a coated tablet in accordance with the present invention; and

• Figure 7 is a side view of a line for making air flow channels through ingestible elements in accordance with the present invention.

15 In Figures 1 to 7, the same references are used to designate the same elements.

Figure 1 shows a tablet 1 containing an active principle, such as aspirin for example, having a channel 3 made through the thickness thereof to interconnect the two main faces 5 and 7 of the tablet. The channel 3  
20 allows air to flow through. Thus, if the tablet 1 should become stuck in a position where it blocks the trachea, the channel 3 allows air to pass through and avoids choking while waiting for the tablet to be evacuated from the airways. By way of example, the channel 3 can be  
25 cylindrical with a diameter lying in the range 0.5 mm to 6 mm, for example, preferably in the range 2 mm to 4 mm, e.g. equal to 2 mm, 3 mm, or 4 mm. Nevertheless, it should be understood that implementing channels having sections in the form of regular or other polygons, etc.,  
30 and also channels of varying sections would not go beyond the ambit of the present invention.

Figure 2 shows a tablet 1 in accordance with the present invention having a plurality of channels 3 distributed around its periphery and advantageously  
35 interconnected, e.g. at the center of the tablet. The tablet of Figure 3 is chunkier in shape making it easier to swallow and it is also provided with channels 3

regularly distributed around its periphery plus a channel 3 interconnecting its main faces 5 and 7. All the channels are interconnected in the center of the tablet 1. Thus, whatever position the tablet might occupy if stuck in the trachea, the lungs remain connected via an air flow channel to the external medium containing air.

Figures 4 and 5 show a capsule 9 whose outer skin is constituted by a first U-tube 11.1 having an outside diameter substantially equal to the inside diameter of a second U-tube 11.2. The tubes are suitable for being engaged one in the other so as to form a tube in the form of a closed loop suitable for receiving microencapsulated particles of the activated principles of the medicine. The space between the walls of the tube forms an air-passing channel 3. The capsule 9 can be substantially toroidal, or on the contrary it can be flattened. In a variant, each of the tubes 11.1 and 11.2 is of varying diameter so that the outside diameter of the tapering end of a first tube corresponds to the inside diameter of the flared end of the other tube, thus enabling the tubes to be engaged in each other.

In a variant, the outer skin of the capsule is constituted by a single tube whose ends are engaged one in the other.

Figure 6 shows an example of a coated tablet 1 in accordance with the present invention comprising an active principle 13' covered by a film 15 for preventing contact with the taste buds (for a medicine of disagreeable taste) or for controlling release of the active principle. By way of example, the film 15 can be based on sugar. Advantageously, the film 15 covers the active principle 13' completely, including inside the channels 3.

Naturally, the present invention is not limited to medicines but also applies to foodstuffs such as, for example, sweets, candies, biscuits, nuts, dry charcuterie, pieces of cheese, ice cubes, sugar lumps,

confectionery, chocolates, and extruded products of the type comprising cocktail nibbles and the like. The elements can be obtained by compression or molding in molds having inserts corresponding to the channels 3.

5 These inserts can be implemented, for example, in the form of rods that are fixed, or moving if that should be necessary to enable unmolding.

For foodstuffs that are not shaped in this way such as hazelnuts, peanuts, cashew nuts, or the like, the  
10 channels 3 are advantageously made by removing material mechanically or thermally. Material is advantageously removed by means of a punch, although drilling, mechanical machining, or laser machining would not go beyond the ambit of the present invention.

15 Figure 7 shows a line for making channels 3 by removing material, advantageously by means of a punch. The line comprises a conveyor 17 fed with ingestible elements 19 by a feeder 21, e.g. a hopper. A mechanical  
20 guide device represented by 23 serves to orient the elements 19, in particular hazelnuts, peanuts, or advantageously, peanut halves.

The elements in which channels 3 are to be made come under a punch 25 (or other removal tool) driven with motion represented by arrow 27 perpendicularly to the  
25 travel direction 29 of the conveyor 17 and synchronized therewith. In a first embodiment, the conveyor 17 moves continuously and the punch 25 acts on moving targets. In a variant, the conveyor brings an element 19 under the punch 25 and then stops while the punch operates. The  
30 movement of the conveyor 17 then restarts and elements 19 with channels 3 are collected in a receptacle 31 for packaging.

The present invention applies to the food industry and also to the pharmaceuticals industry.



## CLAIMS

- 1/ An element suitable for being ingested, comprising at least one air-passing channel (3) making it possible to avoid choking in the event of being swallowed the wrong way.
- 2/ An element according to claim 1, wherein the channel (3) is cylindrical or substantially cylindrical.
- 3/ An element according to claim 2, wherein the channel (3) has a diameter lying in the range 0.5 mm to 6 mm, preferably in the range 1 mm to 4 mm, and more preferably in the range 2 mm to 3 mm.
- 4/ An element according to any preceding claim, wherein said element is a medicine for taking orally.
- 5/ An element according to claim 4, wherein said element is a tablet.
- 6/ An element according to claim 4 or 5, wherein said element is a coated tablet.
- 7/ An element according to claim 6, wherein the coating covers the walls of the air-passing channel (3).
- 8/ An element according to claim 4, wherein said element is a capsule.
- 9/ An element according to claim 8, wherein the capsule comprises an outer skin in the form of a tubular element that is closed to form a loop.
- 10/ An element according to any one of claims 1 to 3, wherein said element is a foodstuff.

## A B S T R A C T

## INGESTIBLE ELEMENTS

5           The invention relates mainly to an element (9)  
suitable for being ingested, the element being  
characterized in that it includes at least one air-  
passing channel (3) making it possible to avoid choking  
in the event of being swallowed the wrong way. The  
10 present invention applies to the food industry and also  
to the pharmaceuticals industry.

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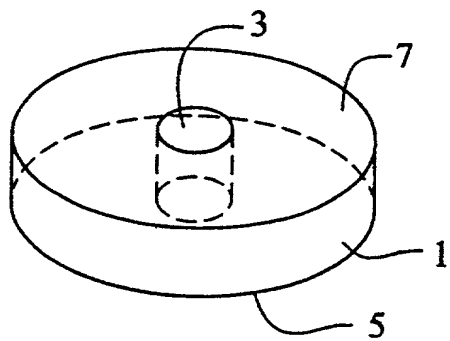


Fig. 1

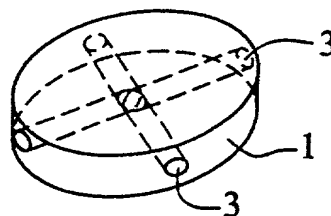


Fig. 2

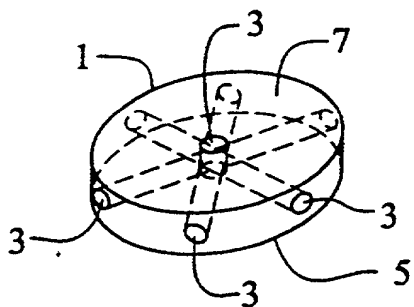


Fig. 3

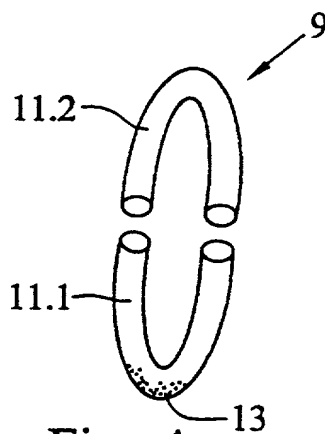


Fig. 4

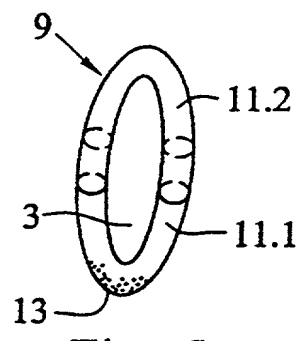


Fig. 5

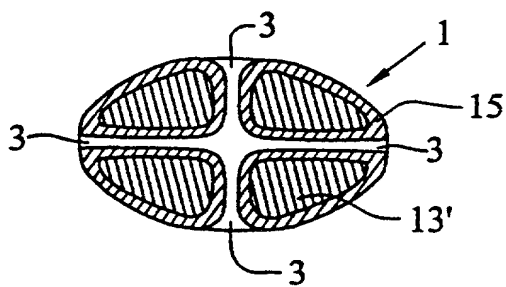


Fig. 6

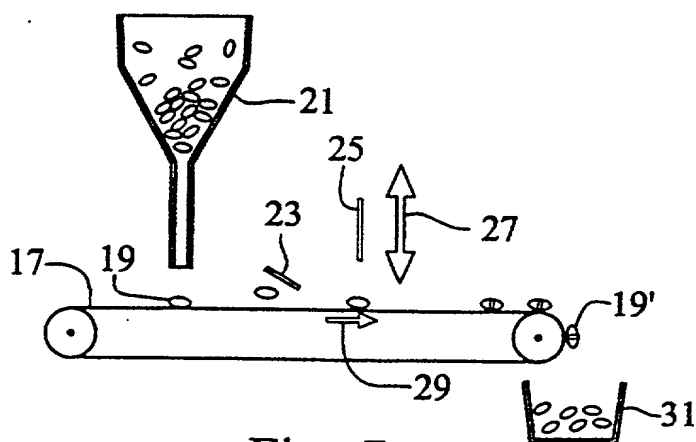


Fig. 7

**DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION**

(Foreign Agent Involved)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**"Ingestible elements"**

the specification of which is attached hereto unless the following box is checked:

☒ [ X ] was filed on June 22, 1999 as United States Application Number or PCT InternationalApplication Number PCT/FR99/01489 and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendments referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

**Prior Foreign Application(s)****Priority Claimed**

<u>98/07838</u>	<u>France</u>	<u>22/06/1998</u>	<input checked="" type="checkbox"/> [ X ]	<input type="checkbox"/> [ ]
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>                    </u>	<u>                    </u>	<u>                    </u>	<input type="checkbox"/> [ ]	<input type="checkbox"/> [ ]
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefits under 35 U.S.C. § 119(c) of any United States provisional application(s) listed below.

                      
(Number)                      
(Filing Date)                      
(Number)                      
(Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(e) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C., § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Appln. Serial No.)

(Filing Date)

(Status—patented/pending/aban.)

(Appln. Serial No.)

(Filing Date)

(Status—patented/pending/aban.)

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from my French representatives, Cabinet Ores, as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change named herein will be so notified by the undersigned.

I hereby appoint the practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence to that Customer Number:

**Customer Number 826**

ADDRESS CORRESPONDENCE TO THE  
ATTENTION OF:  
Raymond O. Linker, Jr.  
Registration No. 26,419

DIRECT ALL TELEPHONE CALLS TO:  
Raymond O. Linker, Jr.  
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Tel (704) 331-6000  
Fax (704) 334-2014

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first/sole inventor:

DOUAIRE Philippe

Inventor's signature

[Signature]

Date: 20/2/01

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Citizenship:

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Post Office Address:

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**VINCENSINI Sandrine**

Date:

21/02/2001

FRANCE

**FRENCH**

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**Inventor's signature**

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**Citizenship:**

**Post Office Address:**

**Inventor's signature**

Date:

**Residence:**

**Citizenship:**

**Post Office Address:**